Tentative Interim Amendments to the TNI Laboratory Accreditation Standards

In May of 2009, The NELAC Institute (TNI) posted 7 Tentative Interim Amendments (TIA) for review and comment by the TNI membership. This document summarizes these seven amendments and their final resolution.

TIA #1 pertains to Volume 3, Sections 10.3, 10.3.1, 10.3.2, 10.3.3, 10.3.4, 10.3.5 and 10.3.6. These sections describe the requirements for scoring by proficiency testing providers (PTP). During the review by the Laboratory Accreditation System Committee (LASC), members of the LASC discovered a conflict between this section and related language in other PT modules. Specifically these sections had not been revised to incorporate the changes in scoring necessary to make possible the change in the reporting of analytical results that were made in Volume 1 Module 1 and the evaluation of PT performance made in V2 Module 2. Hence the sections were revised accordingly and presented for public comment to the TNI membership. Based on the feedback received the section was further revised to clarify several of the examples of application of scoring that were originally presented. The change corrects a circumstance that would have resulted in adverse impact to laboratories if the change were not made. The revised language is shown below.

10.3 Evaluation of Individual Participant Results

10.3.1 If the assigned value is greater than “0” and the acceptance limits are calculated per section 10.2; a reported value shall be evaluated as “Acceptable” if it falls within the acceptance limits. If a reported value falls outside of the acceptance limits it shall be evaluated as “Not Acceptable” unless the reported value meets the conditions of 10.3.2 or 10.3.3 in which case, the reported value shall be evaluated as per the requirements given in these sections.

10.3.2 If an assigned value set to less than (<) the PTRL, any value reported with a less than (<) sign or a reported value of “0” or if the reported numerical value is less than the PTRL, the reported value shall be evaluated as “Acceptable”.

Examples are as follows:

A) If the assigned value is set to “< 10”, any value reported with a “<” i.e.: <5, <10, < 100 shall be evaluated as “Acceptable”.

B) If the assigned value is set to “< 10”, and the reported value of “0” shall be evaluated as “Acceptable”.

C) If the assigned value is set to “< 10”, and the reported value is “5” the data point shall be evaluated as “Acceptable”.

D) If the assigned value is set to “< 10”, and the reported value is “11” the data point shall be evaluated as “Not Acceptable”.

10.3.3 If the assigned value is greater than “0”, any value reported with a less than (<) sign shall be evaluated as “Acceptable”, if the value reported with the less than sign is greater than the lower acceptance limit.

Examples as follows:

A) If the assigned value is set to “10” with a lower acceptance limit of “5”, if the reported value is “< 4” the data point shall be evaluated as the “Not Acceptable”.

B) If the assigned value is set to “10” with a lower acceptance limit of “5”, if the reported value is “< 7” the data point shall be evaluated as the “Acceptable”.

10.3.4 A result shall be evaluated as “No Evaluation” if it cannot be evaluated (e.g. alpha characters for a quantitative test).

10.3.5 Analytes not reported by the laboratory, but included in a PT sample received from the PT Provider shall be evaluated as “Not Reported”.

10.3.6 If the PT Provider invalidates an analyte in a PT study, all evaluations for data reported for that analyte shall be “No Evaluation” and a discussion of the situation leading to the invalidation shall be included in the final report to participant labs and ABs.

TIA #2 pertains to Volume 1, Module 1 Section 7.2. Language in this section used the word “appeals”. The use of this term was chosen by the PT Committee based on a prior understanding that TNI would develop an appeals process. During LASC review it was discovered that some members of the NELAP Board would not vote to approve the standard if the word “appeals” remained in the standard and also that TNI did not have an appeals process nor did TNI intend to develop said process. The LASC recommended that this section be deleted from the standard. The PT Committee agreed to this change under the condition that TNI develop a process for complaint resolution. The Committee was subsequently notified by the TNI Executive Director that a process for complaint resolution between laboratories and Accreditation Bodies (Abs) is under development with the Policy Committee and a procedure will be in place before the implementation date of the TNI Standard. A proposal to delete this section was presented for public comment to the TNI membership. No negative feedback was received. Consequently, Section 7.2 was removed from the standard in its entirety.

TIA #3 pertains to Volume 2, Module 2 Sections 5.1.2, 5.2.1 c), 7.3 d). The language in these sections describes the requirements for the purchase of PT samples and use of PTPA accredited PT providers. The language in these sections was not consistent with similar language presented in Volume 1, Module and this error was overlooked during standards development. These sections were revised to be consistent to Volume 1, Module 1 and presented to the TNI membership for public comment. No negative feedback was received. The revised language is shown below.

Section 5.1.2: The Primary AB shall require that the PT samples for initial accreditation be obtained from any PTPA-accredited PT provider as part of a TNI-compliant PT study, unless there are not any PTPA-accredited PTP for the FoPT in which case the PT sample may be purchased from any PTP and the AB shall accept the results from the PTP selected by the laboratory.

Section 5.2.1 c): The laboratories obtain PT samples from any PTPA accredited PTP unless there are not any PTPA-accredited PTP for the FoPT in which case the

PT sample may be purchased from any PTP and the AB shall accept the results from the PTP selected by the laboratory.

Section 7.3 d): the laboratory submits analytical results for a FoPT from a PT provider that is not accredited by the PTPA unless there are not any PTPA-accredited PTP for the FoPT in which case the PT sample may be purchased from any PTP and the AB shall accept the results from the PTP selected by the laboratory.

TIA #4 pertains to Volume 1, Module 1 Section 4.2.1. During standard review the LASC noticed a clause in Volume 2, Module 2 that was not included in V1M1. The clause includes an allowance to analyze PT samples in the minimum time frame PT samples are available if an PT sample is not available at least two times per year from any PTPA approved PT provider. The LASC recommended that the committee delete the clause in V2M2 to make the modules consistent. After committee review, the group decided the omission of the clause in V1M1 was in error. An amendment to insert the clause in this section was presented for public comment to the TNI membership. No negative feedback was received. Consequently, the clause was added to the standard. The revised language is shown below.

To maintain accreditation the laboratory shall:

a) analyze at least two TNI-compliant PT samples per calendar year for each accreditation FoPT for which the laboratory is accredited unless TNI-compliant PT samples are not available from any PTPA approved PT provider at least twice per year, in which case the laboratory shall analyze the PT samples in the minimum time frame in which the PT samples are available. The analysis dates of successive PT samples for the same accreditation FoPT shall be at least five (5) months apart and no longer than seven (7) months apart unless the PT sample is being used for corrective action to reestablish successful history in order to maintain continued accreditation, or is being used to reinstate accreditation after suspension, in which case the analysis dates of successive PT samples for the same accreditation FoPT shall be at least fifteen (15) days apart.

TIA #5 pertains to Volume 1, Module 1 Section 6.1. During standard review the LASC noticed a clause in Volume 2, Module 2 that was not included in V1M1. The clause includes a specification that the laboratory must notify the PTP when a PT sample is used for corrective action. The LASC recommended that the committee add the clause in V1M1 to make the modules consistent. After committee review, the group decided the omission of the clause in V1M1 was in error. An amendment to insert the clause in this section was presented for public comment to the TNI membership. No negative feedback was received. Consequently, the clause was added to the standard. The revised language is shown below.

…. The following requirements shall apply to the PT sample used to re-establish successful history:

a) The PT sample shall be obtained from any PTPA accredited PTP unless there are not any PTPA-accredited PTP for the FoPT in which case the PT sample may be purchased from any PTP. The laboratory shall notify the PTP that the PT sample will be used for corrective action purposes so the PTP may ensure that the PT sample

supplied meets the requirements for supplemental PT as defined in Volume 3 of this standard.

TIA #6 pertains to Volume 2, Module 2 Section 7.3 a). During standard review the LASC found an implementation problem with the language in this section. Specifically, the use of the phrase "acceptance limits" implied that all PT results must be within a specific range of limits in order to be deemed acceptable. The language is inconsistent with the scoring specifications outlined in Volume 3. The language was revised and presented to the TNI membership for public comment. One comment was received that was specific to how the PTP sets acceptance limits for PT samples. The setting of acceptance limits for PT is the same as it was in the NELAC 2003 standard and the procedure is consistent with the published FoPT tables. None of the TIA's issued were associated with that process, and therefore the comment was non-persuasive. Since no comments specific to this clause were received, the clause was revised as presented. The revised language is shown below.

7.3 The primary AB shall consider the analytical result for a FoPT not acceptable when:

a) the result reported by the laboratory does not meet the criteria for "acceptable" as specified in V3, Section 10.3 and associated subsections of this Standard. If the criteria in V3, Section 10.3 are met, and the result for the FoPT was scored "not acceptable" by the PTP, the AB shall overturn the performance evaluation and score the analytical result "acceptable".

TIA #7 pertains to Volume 1, Module 6, Section 1.7.1c. The affected section deals with short-term background monitoring for radiochemistry. Based on feedback from a laboratory that requested interpretation of the NELAC Standard, a change was made to both clarify and make less burdensome some of the requirements in the Radiological Module. This change results in a standard that is no less effective in monitoring than the previous standard without imparting additional burden on laboratories. The revised language is shown below.

c) Background Measurement

Background measurements shall be made on a regular basis and monitored using control charts or tolerance charts to ensure that a laboratory maintains its capability to meet required measurement quality objectives. (This background measurement is not the short term check for contamination that is addressed in 1.7.1 d). The background measurement values must be subtracted from the total measured activity in the determination of the sample activity.

i) For gamma-ray spectroscopy systems, background measurements shall be performed on at least a monthly basis.

ii) For alpha-particle spectroscopy systems, background measurements shall be performed on at least a monthly basis.

iii) For gas-proportional counters background measurements shall be performed on at least a weekly basis.